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020583  
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EXAMINER	
LEFFERS JR, G	
ART UNIT	PAPER NUMBER

1636  
DATE MAILED:

7  
01/16/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
**09/441,242**

Applicant(s)  
**Russo, et al.**

Examiner  
**Gerald G. Leffers Jr.**

Group Art Unit  
**1636**



☐ Responsive to communication(s) filed on \_\_\_\_\_.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 5-7, 11-19, 22-63, and 65 is/are pending in the application.

Of the above, claim(s) 11, 12, 14-16, 22-63, and 65 is/are withdrawn from consideration.

☒ Claim(s) 18 and 19 is/are allowed.

☒ Claim(s) 5-7, 13, and 17 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☒ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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**DETAILED ACTION***Specification*

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 because sequences were set forth that lack sequence identifiers, no CRF was filed, no corresponding paper sequence was filed and no corresponding attorney statement was filed. For example, these sequences include those given in Figure 11. Also, the amino acid sequence given in Figure 3 does not correspond to SEQ ID NO: 2 in that the sequence given in Figure 3 has an additional methionine residue at the amino terminus not present in SEQ ID NO: 2. If the Sequence Listing required for the instant application is identical to that of another application, a letter may be submitted requesting transfer of the previously filed sequence information to the instant application. For a sample letter requesting transfer of sequence information, refer to MPEP 2422.05. Additionally, it is often convenient to identify sequences in figures by amending the Brief Description of the Drawings section (see MPEP 2422.02).

Applicants are required to comply with all of the requirements of 37 CFR 1.821 through 1.825. *Any* response to this office action that fails to meet all of these requirements will be considered non-responsive. The nature of the noncompliance with the requirements of 37 C.F.R. 1.821 through 1.825 did not preclude the continued examination of the application on the merits, the results of which are communicated below.

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***Election/Restriction***

Applicant's election with traverse of Group I (claims 5-7, 13, 17-19) in Paper No. 5 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

***Drawings***

This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5, 13 and 17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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Claim 5 is drawn towards an isolated TCL-1 protein. Claim 13 is drawn to a fusion protein comprising at least 10 amino acids from a TCL-1 protein linked to a non-TCL-1 protein sequence. Claim 17 is drawn to a method for producing a recombinant TCL-1 polypeptide. The specification teaches that the TCL-1 protein can be that present in many different species, including but not limited to mammalian, bovine, ovine, porcine, equine, rodent and human, in naturally occurring-sequence or in variant form, or from any source, whether natural, synthetic, or recombinant. Thus, these claims are broad genus claims, encompassing a large number of polypeptides from a broad range of different biological species.

The specification teaches that the human TLC-1 gene is located at chromosome 14q32.1, in a region banded by two clusters of breakpoints. The polypeptide sequence for the human protein is described by SEQ ID NO: 2. It is taught that the TLC-1 expression is associated with different pathologies due to chromosomal rearrangement. However, there is no biochemical function described for the human polypeptide and, thus, no structure/function framework described for the human polypeptide which might be applicable to TLC-1 polypeptides from other sources. There is no description in the specification as to whether the TLC-1 gene and polypeptide are conserved across different biological species.

Given that the rejected claims are broad genus claims encompassing a large number of polypeptides for different biological species, the lack of description within the specification as to whether the TCL-1 gene is conserved across different biological species and the lack of guidance regarding possible structural/functional characteristics which might be more or less conserved

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across different biological species, one of skill in the art would not be able to envision a representative number of embodiments in order to describe the claimed genus for each of these claims. Therefore, one of skill in the art would reasonably conclude that applicants were not in possession of the claimed invention for each of the rejected claims.

Claim 7 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 7 is drawn towards any fragment of the polypeptide described by SEQ ID NO: 2 which can be specifically bound by an antibody to a TCL-1 protein. The paper sequence listing describes SEQ ID NO: 2 as a 113 amino acid polypeptide. The specification does not clearly describe the lower limit for what constitutes a fragment of the polypeptide of SEQ ID NO: 2, meaning that the claim can read on a "fragment" of SEQ ID NO: 2 of any length from 1 to 112 amino acids, so long as that fragment is bound specifically by an antibody against TLC-1. Thus, the claim is a very broad genus claim, potentially encompassing an enormous number of polypeptide "fragments" which can be bound by such a TLC-1-specific antibody.

The only relevant example provided by the specification is an example wherein the whole, recombinantly expressed polypeptide was used to generate antisera in rabbits. There is no description in the specification as to what regions or fragments within the whole peptide structure

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were bound by the antibodies generated in this experiment. There is no description within the specification as to which polypeptide fragments derived from SEQ ID NO: 2 will actually bind a TLC-1-specific antibody.

Given the enormous number of species encompassed by this broad genus claim, the functional limitation of being bound by a TLC-1-specific antibody, the lack of description within the specification of which fragments derived from the TLC-1 polypeptide of SEQ ID NO: 2 can be expected to bind such an antibody raised against the entire polypeptide and given the fact that it is commonly known in the art that not all polypeptides (e.g. polypeptide fragments) are antigenic or are antigenic in all presentations (e.g. as part of a 3-dimensional polypeptide versus a linear fragment), one of skill in the art would not be able to envision a representative number of embodiments to describe the claimed genus. Therefore, one of skill in the art would reasonably conclude that applicants were not in possession of the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 6 is vague and indefinite in that it specifies a polypeptide having the amino acid sequence of SEQ ID NO: 2 from amino acid number 1 to 114. In the paper copy of the sequence listing SEQ ID NO: 2 has only 113 amino acids.

### ***Conclusion***

Claims 5-7, 13 and 17 are rejected. Claims 18-19 are allowed.

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald Leffers, Jr. whose telephone number is (703) 308-6232. The examiner can normally be reached on Monday through Friday, from about 9:00 AM to about 5:30 PM. A phone message left at this number will be responded to as soon as possible (usually no later than 24 hours after receipt by the examiner).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Richard Schwartz, can be reached on (703) 308-4003.



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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

DAVID GUZO  
PRIMARY EXAMINER  
*David Guzo*

*G. Leffers, Jr.*

G. Leffers, Jr.

Patent Examiner

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January 11, 2001